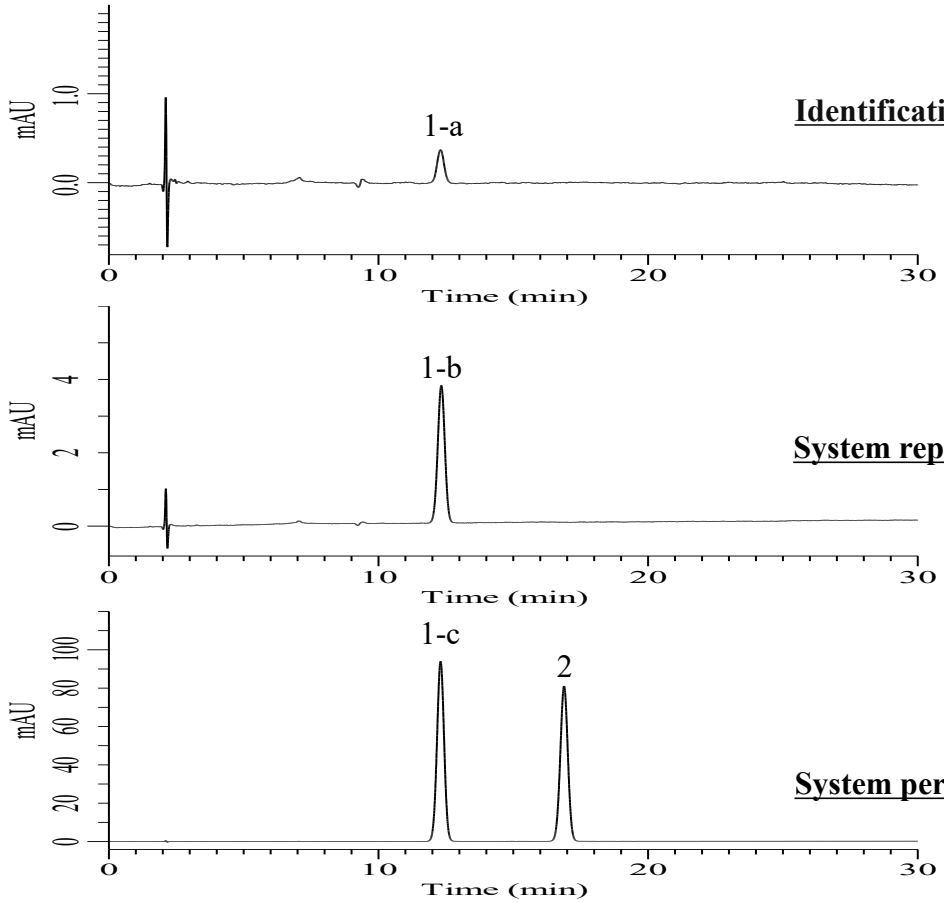
Analysis of Rebamipide

(Under the Condition of the Japanese Pharmacopoeia 18th, Rebamipide, Purity(4)Related Substances)



Conditions

System	:	Primaide (HITACHI)
Column	:	Inertsil ODS-3 (GL Sciences Inc.) (5 µm, 250 x 4.6 mm I.D.)
Column Cat. No.	:	5020-01732
Eluent	:	A) CH_3OH B) Buffer* C) H_3PO_4 A/B/C = 100/100/1, v/v/v
Flow Rate	:	1.25 mL/min
Col. Temp.	:	40 °C
Detection	:	UV 232 nm (Primaide 1435 DAD)
Injection Vol.	:	10 µL
Sample	:	Standard in Water / 0.05 M Phosphate buffer (pH 6.0) / Methanol mixture (7 : 7 : 6)

*Dissolve 2.44 g of sodium 1-decanesulfonate in 1000 mL of water and to this solution add 1000 mL of methanol and 10 mL of phosphoric acid.

Analyte:

1-a. Rebamipide	: 0.16 mg/L
1-b. Rebamipide	: 1.6 mg/L
1-c. Rebamipide	: 40 mg/L
2. 4-Chlorobenzoic acid	: 40 mg/L

The peak ratio of 1-a/1-b (%) : (7 ≦) 9.6 (≦ 13)

RSD of the peak area of 1-b (%)(n=6) : 0.18 (≦ 2.0)

Resolution (1-c, 2) : 9.1 (≧ 8)